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June 6, 2025

Via ECF
Honorable Evelyn Padin, U.S.D.J.
United States District Court
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07101

Re: Novartis v. Novadoz et als.
Civil Action No. 2:25-cv-00849-EP-JRA

Dear Judge Padin:

We, along with our co-counsel at Jenner & Block LLP and Daignault Iyer LLP, represent Defendants Novadoz Pharmaceuticals LLC, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited (collectively, "MSN") in the above matter. We write in response to Novartis's letter of June 5, 2025 (ECF 54) regarding the Third Circuit's June 4, 2025 Order granting a limited remand (ECF 53; the "Remand Order").

First, in light of the remand, the Court should reconsider its March 17, 2025 opinion (ECF No. 32; the "PI Opinion") and deny Novartis's motion for a preliminary injunction, for all the reasons briefed at length by MSN. In its May 22, 2025 Opinion granting a stay of the injunction pending appeal (ECF No. 51; the "Stay Opinion"), the Court recognized that Novartis was *unlikely* to succeed on the merits of its trade dress claim and *unlikely* to suffer irreparable harm absent an injunction. *See* Stay Opinion at 5–17. While the Court concluded it did not have jurisdiction to take the further step of *sua sponte* reconsidering the PI Opinion and denying the motion for a preliminary injunction entirely, *see id.* at 4 n.1,[1] the Third Circuit's limited remand removes this obstacle. *See* Fed. R. Civ. P. 62.1(c). Now that it has jurisdiction to do so, the Court should reconsider its PI Opinion and deny Novartis's motion for a preliminary injunction for the reasons set forth in its Stay Opinion, following which MSN will promptly dismiss its appeal.

Second, the Court should deny Novartis's request for an injunction pending appeal. ECF 54 at 1 (citing Fed. R. Civ. P. 62(d)). "[T]he standard for obtaining an injunction pending appeal

[1] The Court's holding that it lacked jurisdiction to reconsider its order granting Novartis's motion for a preliminary injunction was consistent with the position taken by MSN in its reconsideration briefing. *See* ECF 45 at 7.

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is essentially the same as the standard for obtaining a preliminary injunction and all four factors must be met," including a likelihood of success on the merits and irreparable harm. *Robinson v. Murphy*, 2020 WL 13891018, at *1 (D.N.J. Oct. 28, 2020) (denying motion for injunction pending appeal). The Court, however, has already concluded in its Stay Opinion that Novartis does not satisfy this standard. The Court has held that Novartis is not likely to succeed on the merits of its claim because the claimed product features are functional and thus categorically unprotectable as trade dress. Stay Op. at 5–12. The Court expressly found that "for the pendency of MSN's appeal, MSN's evidence persuasively shows that irreparable harm to Novartis is unlikely." *Id.* at 13.[2] On the other side of the balance of harms, the Court reaffirmed its earlier finding that "[t]here is no question that MSN would suffer significant hardship if enjoined." *Id.* at 17. Finally, the Court found that the public interest does not favor an injunction, reiterating its prior statement that it was "mindful of the societal benefits of affordable alternatives to brand-name drugs and laments the obstacles to such access." *Id.* Any order granting an injunction pending appeal would be entirely inconsistent with these carefully reasoned findings, which Novartis's letter provides no basis (such as new facts or changed circumstances) to revisit.

We appreciate the Court's attention to this matter.

Respectfully submitted,

/s/ Rebekah Conroy
Rebekah Conroy

RRC/btr
cc: Counsel of Record via ECF

[2] As the Court recalls, both the Delaware and D.C. district courts have rejected Novartis's claims of irreparable harm. *Novartis Pharms. Corp. v. Becerra*, 2024 WL 3823270, at *4 (D.D.C. Aug. 13, 2024) ("Novartis asserts that it will suffer economic losses from a dramatic reduction in sales after MSN's generic entry. . . . The present record does not establish that the introduction of MSN's generic will threaten the viability of Novartis's business or cause such 'extreme' hardship as to justify injunctive relief." (citation omitted)); *In re Entresto (Sacubitril/Valsartan) Pat. Litig.*, 2024 WL 3757086, at *3–4 (D. Del. Aug. 12, 2024) ("I am skeptical about Novartis's characterization of many of its potential harms. . . . Novartis has not established irreparable harm.").